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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/982,299 | 10/16/2001 | Timothy R. Ryan | M190.137.101 | 7830 |

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02/09/2005

DICKIE, BILLING & CZAJA, PLLC
FIFTH STREET TOWERS, SUITE 2250
100 SOUTH FIFTH STREET
MINNEAPOLIS, MN 55402

EXAMINER

MATTHEWS, WILLIAM H

ART UNIT

PAPER NUMBER

3738

DATE MAILED: 02/09/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|---|-----------------------------|--|
| Office Action Summary | Application No. 09/982,299 | Applicant(s) RYAN ET AL. | |
| | Examiner William H. Matthews (Howie) | Art Unit 3738 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 November 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 and 37-47 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-9 and 12-16 is/are allowed.
- 6) ☒ Claim(s) 10, 11 and 37-47 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f):
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

Applicant's arguments filed 11-18-04 have been considered but are not persuasive.

With regard to claims 1-9 and 12-16, all prior rejections have been withdrawn.

With regard to claims 10-11 and 37-43 in view of Wright et al., Applicant contends Wright et al. lacks discrete markings corresponding to eyelet locations. Examiner disagrees because figures 2 and 10 clearly show colored sutures 31,32,33,34 identifying eyelet locations.

Specification

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: claim 45 recites a middle portion, first point, second point, and linear distance that are not described in the specification or drawings.

Claim Rejections - 35 USC § 112

Claim 45 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The use of the terms middle section, first point,

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second point, and the linear distance, as used in claim 45, are not described in the specification.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 11-12 and 37-44 are rejected under 35 U.S.C. 102(b) as being anticipated by Wright et al. US PN 5,306,296.

Wright et al. discloses in figures 2 and 10 and line 48 of col. 13 through line 66 of col. 14 annuloplasty devices comprising a fabric sheath and radiopaque arcuate stiffening wire 35 entirely disposed within the sheath having a thickness less than about 3.0 mm and ends bent back on itself to form eyelets. Markers 31,32,33,34 are located at the eyelets. Figure 4B shows a stiffening element configured to independently maintain a generally saddle shape in a Z-plane and arcuate in X and Y planes. With regard to claim 44, the stiffening element defines an entire perimeter shape of the sheath at the location of the stiffening element.

3. Claims 10, 37,38,42-45,47 are rejected under 35 U.S.C. 102(b) as being anticipated by Campbell US PN 6,102,945.

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Campbell discloses in figures 3,5,6 and lines 8-54 of col. 4, and lines 1-61 of col. 5 an annuloplasty device comprising a polyester sheath and arcuate stiffening element 22 having eyelets 28 at the ends and entirely disposed within the sheath. Markers 116 are located at the eyelets. With regard to claim 44, the stiffening element defines the perimeter shape of the entire sheath perimeter. With regard to claim 45, figure 6 shows a length along a middle section being greater than a length between the eyelets. Furthermore it is noted that due to flexibility of the annuloplasty band, the band is capable of bending to a further degree than shown.

4. Claims 10, 37,38,42-45,47 are rejected under 35 U.S.C. 102(b) as being anticipated by Gross US PN 5,824,066.

Gross discloses in figures 1-2 and lines 16-67 of col. 2, and lines 36-42 of col. 4 an annuloplasty device comprising a dacron sheath 10 and arcuate stiffening element 30,32 having eyelets 48,54 at the ends and entirely disposed within the sheath. Markers 73,55 are located at the eyelets. With regard to claim 44, the stiffening element defines the perimeter shape of the entire sheath perimeter. With regard to claim 45, figure 2 shows a length along a middle section being greater than a length between the eyelets.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

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invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claim 46 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wright et al. US PN 5,306,296.

Wright et al. discloses an annuloplasty device meeting the structural limitations of claim 46 as described above in the rejection of claim 37, but lacks the express disclosure of the marking on the sheath comprising a cross. At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to provide a marking in the shape of a cross because Applicant has not disclosed that a cross shape provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with an encircling line about the sheath because both markings enable the surgeon to identify a location of the sheath.

Therefore, it would have been an obvious matter of design choice to modify Wright et al. in order to obtain the invention as specified in claim 46.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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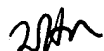
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to William H. Matthews (Howie) whose telephone number is 571-272-4753. The examiner can normally be reached on Monday-Friday 10-6:30PM.

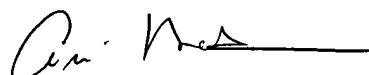
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine M. McDermott can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



WHM
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CORRINE McDERMOTT
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700